REMARKS

In the Office Action dated January 9, 2004, Claims 1-28 are pending. The Examiner has made the restriction requirement final. Therefore, Claims 8-9 and 28 are under consideration. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter.

This Response addresses each of the Examiner's objections and rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The title of the invention has been objected to as allegedly not descriptive. The Examiner requires a new title that is clearly indicative of the invention to which the claims are directed. In response, Applicants have provided a new title, as requested by the Examiner. The new title is clearly indicative of the invention to which the claims are directed.

Claims 8 and 28 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Coval (U.S. Patent No. 4,093,606). Specifically, the Examiner alleges that Coval teaches the production of gamma globulin suitable for intravenous administration that comprises Fraction II + III. The Examiner contends that a composition for intravenous administration taught by Coval is a pharmaceutical composition. The Examiner further indicates that Coval discloses that the reference to Fraction II + III is to Cohn Fraction II + III.

In the first instance, Applicants have canceled Claim 9 and amended Claims 8 and 28. Claims 8 and 28, as amended, delineate the products as "irradiated" and "suitable for oral administration." Support for the amendment can be found throughout the specification, e.g., on page 7, line 18 to page 8, line 2, and original Claim 9.

Applicants submit that Coval merely discloses gamma globulin suitable for intravenous administration that comprises Fraction II + III. Nowhere does Coval teach or suggest a pharmaceutical composition or a composition "suitable for oral administration" that includes irradiated Cohn Fraction II+III, as claimed.

Therefore, Claims 8 and 28, as amended, are not anticipated by Coval. The rejection of Claims 8 and 28 under 35 U.S.C. 102 (b) is overcome and withdrawal thereof is respectfully requested.

Claims 8 and 28 have also been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Stolle et al. (EP 0 064 210 B2).

Applicants observe that Stolle et al. merely teach pharmaceutical compositions for oral administration where the composition comprises immune globulin of which at least 70% is IgG. Applicants also observe that Stolle et al. suggest that the immunoglobulin may be Cohn Fraction II + III. Nowhere do Stolle et al teach or suggest a pharmaceutical composition or a composition "comprising irradiated Cohn Fraction II+III" as recited in Claim 8 and 28.

Accordingly, Claims 8 and 28, as amended, are not anticipated by Stolle et al. The rejection of Claims 8 and 28 under 35 U.S.C. 102 (b) is overcome and withdrawal thereof is respectfully requested.

Claims 8-9 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over either Coval or Stolle et al. in view of Miekka et al. (Haemophilia 4:402-408, (1998)). Specifically, the Examiner alleges that each of the Coval and Stolle et al. references teaches a pharmaceutical composition comprising Cohn Fraction II + III. The Examiner admits that neither Coval nor Stolle et al. teach a pharmaceutical composition comprising Cohn Fraction II + III that is irradiated. However, the Examiner alleges that Miekka et al. teach that at the time the

invention was made, the art recognized the need to eliminate non-enveloped viruses from biologics including intravenous immunoglobulin (IGIV), and that gamma irradiation was one method of eliminating these pathogens from plasma-derived biologics used as pharmaceuticals. The Examiner then concludes that the ordinary artisan at the time the invention was made would therefore have found it obvious and would have been motivated to irradiate the pharmaceutical compositions of either Coval or Stolle et al. The Examiner contends that one skilled in the art at the time the present invention was made would have recognized that the method taught by Miekka et al. could be applied to Cohn Fraction II + III because "IGIV is, like Cohn Fraction II + III, a pharmaceutical composition comprising immunoglobulins including IgG." (Emphasis added)

Applicants observe that Miekka et al. merely disclose that plasma-derived proteins are used in replacement therapy for haemophilia and other congenital acquired deficiency conditions. See the first paragraph of the introduction of Miekka et al., on page 402. The need to irradiate these plasma-derived proteins arises from the safety concern of blood transfusion diseases during intravenous administration of IGIV. *Id.*

Accordingly, Applicants submit that there is no teaching or suggestion in Coval, Stolle and Miekka that would motivate one skilled in the art to make irradiated Cohn Fraction II+III for oral administration. Applicants respectfully submit that the rejection of claimed subject matter under 35 U.S.C. §103 requires that the suggestion to carry out the claimed invention must be found in the prior art, not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 492, 20 U.S.P.Q. 1438, 1442 (Fed. Cir. 1991).

Further, Applicants observe that there is no indication that IGIV disclosed in Miekka et al. is a Cohn Fraction II+III. Notably, the Examiner admits that IGIV of Miekka et al.

is "like Cohn Fraction II+III," i.e., not Cohn Fraction II+III, in fact. See the Action, page 4. Thus, even assuming, *arguendo*, that one skilled in the art was motivated to irradiate Cohn Fraction II+III at the time the present application was filed, there was no expectation of success in view of Miekka et al. One might infer, as the Examiner does, that Cohn Fraction II+III might have similar sensitivity as that of IGIV. But such inference is unfounded based on the teaching of Miekka et al. and is pure speculation. Indeed, Miekka et al. admit that protein formulation can modify the sensitivity of virus to radiation damage and that any change in protein formulation may prevent inactivation of viruses during gamma irradiation. See Miekka et al., last paragraph of Discussion, on page 407.

Moreover, even if the IGIV of Miekka et al. is a Cohn Fraction II+III, the IGIV is, at best, a pharmaceutical composition suitable for intravenous administration. Coval and Stolle et al. in view of Miekka et al. do not teach or suggest a pharmaceutical composition comprising irradiated IGIV and a pharmaceutically accepted carrier suitable for oral administration, e.g., Cohn Fraction II+III incorporated with excipients in form of ingestion tablets. See, e.g., the specification, on page 16, lines 1-11.

Thus, Applicants respectfully submit that any connection between certain IGIV that is irradiated for intravenous administration to avoid blood transfusion diseases and the pharmaceutical composition comprising irradiated Cohn Fraction II+III suitable for oral administration is purely conincidence. A conclusion that gamma irradiation will inactivate viruses in the formulation of Cohn Fraction II+III, based on Miekka et al. alone, would rest on speculation or conjecture. "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, or within the

general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corporation v. Lydall, Inc.*, 48 USPQ 2d 1321, 1329 (Fed. Cir. 1998).

Accordingly, in view of the amendment to Claims 8-9, it is respectfully submitted that the present invention is non-obvious over Coval or Stolle et al. in view of Miekka et al. Therefore, the rejection of Claims 8-9 under 35 U.S.C. 103(a) is overcome and withdrawal thereof is respectfully requested.

Claims 8 and 9 have been provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of Claims 8 and 9 of copending Application No. 09/672,911.

In response, Applicants submit that Claims 8 and 9 of copending Application No. 09/672,911 will be cancelled in the event that Claims 8 and 9 of the present invention are allowed.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343
PIB/ZY:ab